510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K043385

B. Purpose for Submission:

New Device

C. Measurand:

Human chorionic gonadotropin

D. Type of Test:

Qualitative

E. Applicant:

Genzyme Corporation

F. Proprietary and Established Names:

OSOM hCG Combo T**est**

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1155

2. Classification:

   Class II

3. Product code:

   JHI

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   The OSOM® hCG Combo Test is a rapid immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum as an aid in the early determination of pregnancy. This test is for professional use in physicians' offices and clinical laboratories.

2. Indication(s) for use:

   The OSOM hCG Combo test is a rapid immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum as an aid in the early detection of pregnancy. This test is for use in physicians' offices and clinical laboratories.

3. Special conditions for use statement(s):

   This device is for physicians' offices and clinical laboratories.

4. Special instrument requirements:

   None

I. Device Description:

The OSOM® hCG Combo Test kit contains 30 OSOM test devices and 30 disposable pipettes. The test devices are composed of a membrane coated with rabbit polyclonal anti-alpha hCG and a conjugate pad containing mouse monoclonal anti-beta hCG.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Quidel QuickVue®+ One-Step hCG Combo Test

2. Predicate 510(k) number(s):

   K020801

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Qualitative detection of	Same

Similarities		
Item	Device	Predicate
	hCG for early detection of pregnancy	
Specimen	Urine or serum	Same
Assay Format	Lateral flow immunoassay	Same
Antibodies	Monoclonal and polyclonal antibodies	Same
Result Read Time	3 minutes for urine 5 minutes for serum	Same
Analytical Sensitivity	20 mIU/mL (urine) 10 mIU/mL (serum)	Same

Differences		
Item	Device	Predicate
Antibody's Biological Source	Rabbit polyclonal	Goat polyclonal

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

The OSOM hCG Combo Test is a solid phase, sandwich-format immunochromatographic assay. Urine or serum is added to the sample well of the Test Device using the pipette provided. The sample migrates through reaction pads where hCG, if present in the sample, binds to a monoclonal anti-hCG dye conjugate. The sample then migrates across a membrane towards the results window, where the labeled hCG complex is captured at a test line region containing immobilized rabbit anti-hCG. Excess conjugate will flow past the test line region and be captured at a control line region containing an immobilized antibody directed against the anti-hCG dye conjugate (with or without hCG complexed to it).

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

a. *Precision/Reproducibility:*

See "Other clinical supportive data" on proficiency testing below.

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

WHO 3rd I.S. 75/537

d. *Detection limit:*

Ten samples of hCG spiked into negative (non-pregnant) urine/serum matrix was tested and read by three technicians following the procedure in the package insert. The OSOM hCG Combo Test will detect hCG concentrations of 20 mIU/mL or more in urine and 10 mIU/mL or more in serum, calibrated against WHO 3rd IS 75/537. Specimens containing 1,000,000 mIU/mL (spiked with purified hCG) will also give positive results.

e. *Analytical specificity:*

Luteinizing hormone (300 mIU/mL), follicle stimulating hormone (1000 mIU/mL), and thyroid stimulating hormone (1000 μIU/mL) were added to negative urine and serum specimens and gave negative results in the OSOM hCG Combo Test.

Various prescription and over-the-counter drugs and urine and serum metabolites were added to specimens containing 0 and 20 mIU/mL (urine) or 10 mIU/mL (serum) hCG. The substances at the concentrations listed in the package insert were not found to affect the performance of the test.

f. *Assay cut-off:*

See "Detection limit" above.

2. Comparison studies:

a. *Method comparison with predicate device:*

Urine specimens from 634 individuals were evaluated with the OSOM hCG Combo Test and the QuickVue®+ One-Step hCG-Combo Test. Samples were from patients seeking confirmation of pregnancy. The two assays were in agreement on 629 of the 634 samples. The DPC Coat-A-Count® hCG IRMA Kit was used to quantify the five discrepant results. Three of the discrepant

samples were found to have an hCG concentration greater than 0 but less than 20 mIU/mL, the stated analytical sensitivity of both assays, and thus were removed from the analysis. One sample contained 0 mIU/mL according to the IRMA and was scored negative by the OSOM test but positive by QuickVue+. The remaining sample contained >500 mIU hCG/mL according to the IRMA and was scored positive by the OSOM test but negative by QuickVue+.

The OSOM hCG urine procedure had greater than 99% agreement with the comparative test methods.

	Comparative Methods (QuickVue+ and IRMA)	
OSOM hCG Combo	+	-
+	196	0
-	0	435

Serum specimens from 691 individuals were evaluated with the OSOM hCG Combo Test and the QuickVue®+ One-Step hCG-Combo Test. Samples were from patients seeking confirmation of pregnancy. The two assays were in agreement on 679 of the 691 samples. The DPC Coat-A-Count® hCG IRMA Kit was used to quantify the twelve discrepant results. Eleven of the discrepant samples were found to have an hCG concentration greater than 0 but less than 10 mIU/mL, the stated analytical sensitivity of both assays, and thus were removed from the analysis. The remaining sample contained 0 mIU/mL according to the IRMA and was scored positive by the OSOM test but negative by QuickVue+.

The OSOM hCG serum procedure had greater than 99% agreement with the comparative test methods.

	Comparative Methods (QuickVue+ and IRMA)	
OSOM hCG Combo	+	-
+	131	1
-	0	548

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. *Clinical specificity**:***

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Urine and serum testing formats were also evaluated at three physician's offices and a clinical laboratory using a proficiency panel. A total of 80 samples were tested at each site. Purified hCG was spiked into horse serum as well as an artificial urine matrix. Each set (40 urine and 40 serum samples) contained negative, low positive, moderate positive, and high positive samples. Each set was tested at each site over the course of three distinct runs. One hundred percent (100%) of the positive and negative results obtained by the POL operators on both urine and serum samples were in agreement with the expected values and with the results obtained by the clinical laboratory operators.

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

The expected values were based on literature.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.